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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,870	07/24/2006	Iris Bahir	1120-PCT-US	1448
7590 Albert Wai-Kit Chan Law Offices of Albert Wai-Kit Chan World Plaza Suite 604 141-07 20th Avenue Whitestone, NY 11357			EXAMINER ZHENG, LI	
			ART UNIT 1638	PAPER NUMBER
			MAIL DATE 10/16/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/550,870

**Applicant(s)**

BAHIR ET AL.

**Examiner**

LI ZHENG

**Art Unit**

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 49-68 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 49-68 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. Claims 49-68 are pending.

***Continued Examination Under 37 CFR 1.114***

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 21, 2008 has been entered.
3. Applicant's cancellation of claims 25-48 and submission of new claims 49-68 filed on 7/21/2008 are acknowledged and entered.

Claims 49-68 are examined on the merits.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. The rejections and objections that are not recited in this Office Action are considered as being withdrawn.

***Claim Rejections - 35 USC § 112***

***New Matter***

6. Claims 49-68 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

New claim 49 contains a limitation of "a monotonous repeat of two to six nucleotides". Such limitation constitutes new matter which is not supported by specification. Applicants are required to point to support for "a monotonous repeat of two to six nucleotides" or to amend the claims to delete the NEW MATTER.

Applicants fail to respond to the new matter rejection

7. Claims 49, 52-60 and 63-68 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in

the Office action mailed March 20, 2008. Applicants traverse in the paper filed July 21, 2008. Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that all the sequences recited in the claims have been described in the specification and Examples show that SEQ ID NO: 1-5 were used to generate plants shown in Figures 2-7(response, page 8, 2<sup>nd</sup> paragraph and 3<sup>rd</sup> paragraph).

The Office contends that Applicants fail to describe a representative number of the claimed MS-like sequences encompassing monotonous repeats of two to six nucleotides. For example, there could be over four thousand of possible variants for a six nucleotides sequence, while the specification only describes one species, (AAGTTC)<sub>n</sub>, in the genus. Further, there is no species disclosed for monotonous repeats of five nucleotides. Claim 49 limits the monotonous repeat to 11 species as listed, however, no length limitation is provided.

Further, for a given two to six nucleotides sequence, it is also unclear how long the repeat would be. Applicants argue that support can be found in the specification page 7, 2<sup>nd</sup> paragraph and that claims 51 and 60 recite the repeating sequence as between 70 and 120 nucleotide long (response, page 9, 2<sup>nd</sup> paragraph).

The Office contends that the specification indicates that the length could be between 12-10,000 nucleotides. However, the examples (i.e. SEQ ID NO: 1-5) provided are all about 90 bp and thus do not represent the broad range as claimed. Further, claims 49, 52-59 do not recite the repeating sequence as between 70 and 120 nucleotide long.

8. Claims 49, 51-61 and 63-68 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for the generation of genetically diverse plants via the incorporation of one of the exogenous microsatellite(MS) sequences of SEQ ID NO: 1-5, does not reasonably provide enablement for a method for the generation of genetically diverse plants via the incorporation of any exogenous microsatellite (MS) sequence into the plant genome. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims, for the reasons of record stated in the Office action mailed March 20, 2008. Applicants traverse in the paper filed July 21, 2008. Applicants' arguments have been fully considered but were not found persuasive.

Applicants first present similar argument as discussed in the written description rejection (response, the paragraph bridging pages 9-10 and page 10, 1<sup>st</sup> paragraph). Therefore, for the similar reason as discussed above, Applicants' argument is not persuasive.

Applicants further argue that a person skilled in the art would regard a monotonous repeat of five nucleotides as a clear extension of the method of the invention, which is possible to arrive at without undue experimentation (response, page 10, 1<sup>st</sup> paragraph).

The Office contends that without further guidance on why transforming MS-like sequence can produce surprising results as Applicants claimed, there is undue trial and

error to test all the different permutations and sequences of different length. For example, there are thousands of variants for two to six nucleotides, whereas for each nucleotide, there are thousands of repeat variants due to different length of the repeat.

***Claim Rejections - 35 USC § 102***

9. Claims 49 and 59 are rejected under 35 U.S.C. 102(e) as being anticipated by Havukkala et al. (US Patent Application Publication Number 2003/0018185).

The claim is drawn to a method for the genetically diverse plants via the incorporation of exogenous microsatellite (MS) sequence comprising a monotonous repeat of AT/TA into the plant genome comprising introducing MS-like DNA fragments into plant cells and selecting and cultivating plants comprising said DNA fragments; or wherein optionally the MS-like DNA fragments obtained in step (a) are ligated into suitable vectors and then proceed to step (b).

Havukkala et al. teach a monotonous repeat of AT/TA (SEQ ID NO: 1), which comprising 7 copies of AT dinucleotides. Havukkala et al. further teach that DNA constructs can be used to introduce microsatellite markers into transgenic plant [paragraph [0064]]. According to the definition of microsatellite (paragraph [0041]), the term refers to an array of tandemly repeated nucleotide motifs wherein each motifs consists of between 2 and about 10 base pairs. The plant would be inherently produced by the method. Therefore, the reference teaches all the limitations set forth by the claims.

Applicants argue that the introduction of microsatellite markers into transgenic plants is mentioned in the discussion for the purpose of polymorphic identification however no phenotypically diverse plants were generated in Havukkala et al. (response, the paragraph bridging pages 11-12 and the paragraph bridging pages 12-13).

The Office contends that Havukkala et al. may perform the experiment with different purpose, however the method of Havukkala et al. comprise the same steps as the instant invention since phenotypically diverse plants were have been inherently generated by the method of Havukkala et al.

***Claim Rejections - 35 USC § 103***

10. Claims 49, 51-61 and 63-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Havukkala et al. (US Patent Application Publication Number 2003/0018185) as for claims 49 and 59, in view of Gallardo et al. (1999, Planta 210:19-26).

The claims are drawn to a method for the genetically diverse plants via the incorporation of exogenous microsatellite (MS) sequence comprising a monotonous repeat of two to six nucleotides into the plant genome comprising introducing MS-like DNA fragments into plant cells and selecting and cultivating plants comprising said DNA fragments; or wherein optionally the MS-like DNA fragments obtained in step (a) are ligated into suitable vectors and then proceed to step (b); or wherein the DNA fragments



are from about 70 to about 120 bp in length; or wherein the exogenous MS is preferably introduced concomitantly with a selective marker of a kanamycin resistant gene; or wherein said DNA fragment is introduced via any one of electroporation, chemical, mechanical means or liposomes; wherein said DNA fragment is introduced by a genetic vehicle such as a plasmid or a viral vector; or wherein said DNA fragment is obtained via synthesis or cloning; wherein said exogenous DNA is produced by the ligation of several DNA pieces; or wherein the generation of genetically diverse plants further includes the generation of one of cells, seeds or progeny of said plants; or a plant variety produced by the method of claim 25, and cells, seeds and progeny thereof.

The Office interprets that "mechanical means" of transformation encompasses any transformation methods.

The teaching of Havukkala et al. is discussed as above.

Havukkala et al. do not teach that the exogenous MS is preferably introduced concomitantly with a selective marker of a kanamycin resistant gene; or that said DNA fragment is introduced via any one of electroporation, chemical, mechanical means or liposomes; or that said DNA fragment is introduced by a genetic vehicle such as a plasmid or a viral vector; or that said exogenous DNA is produced by the ligation of several DNA pieces; or that the DNA fragments are from about 70 to about 120 bp in length; or that the generation of genetically diverse plants further includes the generation of one of cells, seeds or progeny of said plants; or a plant variety produced by the method of claim 25, and cells, seeds and progeny thereof.

Gallardo et al. teach a binary vector with kanamycin resistant gene as selection marker (Figure 1). Gallardo et al. teach that GS cDNA was cloned by ligation (page 20, paragraph bridging left and right columns). Gallardo et al. teach regeneration of transgenic pine tree (page 20, 3<sup>rd</sup> paragraph).

Given the recognition of those of ordinary skill in the art of the value of introducing microsatellite sequence isolated from pine into transgenic plant as taught by Havukkala et al (paragraph [0064]), it would have been obvious for a person with ordinary skill in the art to clone the microsatellite sequence of Havukkala et al. into the binary vector of Gallardo et al. and further transform the resultant vector into the pine tree according to the teaching of Gallardo et al. One skilled in the art would have been motivated to do so given that the transformation vector and method as taught by Gallardo et al. is an obvious choice for introducing microsatellite sequences into transgenic pine tree.

Although the combined teachings do not teach the that the DNA fragments are from about 70 to about 120 bp in length, there are regarded as obvious variants of monotonous repeat. Although the combined teachings do not teach the plants produced, the plants would have been obviously produced by the combined method.

Thus the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

Applicants traverse in the paper filed July 21, 2008. Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that a person with ordinary skill in the art would have no incentive, from the teachings of Havukkala, to generate phenotypically diverse plants (response, the paragraph bridging pages 13-14).

The Office contends that Havukkala et al. do not have to have the same purpose as that of the instant invention in order to result in the instant invention in combination with Gallardo et al.

### ***Summary***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031. The examiner can normally be reached on Monday through Friday 9:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Li Zheng/

Examiner, Art Unit 1638